

ABSTRACTPROCESS FOR THE PRODUCTION OF *N*-(2,6-DIMETHYL-PHENYL)-2-PIPERAZIN-1-YL -ACETAMIDE.5

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The present invention relates to a novel process, suitable for industrial exploitation for the production of *N*-(2,6-dimethyl-phenyl)-2-piperazin-1-yl -acetamide, also known as *N*-lidocaine, obtained from the reaction of piperazine with *N*-haloacetyl-2,6-xylidine.

10 The process comprises the consecutive steps a) through f) :

a) reacting piperazine with *N*-haloacetyl-2,6-xylidine in a molar ratio between about 1/1 and about 6/1 in an aqueous solvent in which has been dissolved an equimolar amount of HCl ;

b) separating the solid formed in step a) from the reaction mixture ;

15 c) neutralizing the filtrate ;

d) extracting the filtrate with a solvent which is not or only to a small extent miscible with the aqueous solvent mentioned in step a) ;

e) crystallizing the *N*-(2,6-dimethyl-phenyl)-2-piperazin-1-yl-acetamide from the solvent mentioned in step d) and

20 f) separating the solid obtained in step e) from the solvent mentioned in step d).